Mechanical interdental cleaning for preventing and controlling periodontal diseases and dental caries

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[Intervention Protocol]

Mechanical interdental cleaning for preventing and controlling periodontal diseases and dental caries

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of mechanical interdental cleaning (flossing, interdental brushing, tooth cleaning sticks and stimulators, oral irrigators), in addition to toothbrushing, compared with toothbrushing alone, for the prevention and control of:

1. periodontal diseases (gingivitis and periodontitis)

2. dental caries

3. dental plaque

This also includes assessing the safety of mechanical interdental cleaning procedures, in terms of harms and adverse effects, balancing important benefits against important harms.

A secondary objective will compare the different mechanical cleaning procedures with each other.

BACKGROUND

Effective oral hygiene is a crucial factor in maintaining good oral health, which is in turn associated with overall health and health-related quality of life (McGrath 2002; Sheiham 2005). Poor oral health may affect appearance in terms of stained or missing teeth; can contribute to bad breath (Morita 2001); and negatively influence self confidence, self esteem and the ability to communicate (Exley 2009). Poor oral health is often accompanied by pain arising from carious lesions which may lead to discomfort when eating, drinking and speaking (Dahl 2011). Individuals with high levels of dental plaque, after accounting for gender, socio-economic status and attendance frequency, are more likely to experience dental caries and periodontal disease (Broadbent 2011).

Dental plaque-induced gingivitis and incipient, non-cavitated carious lesions are reversible (Mariotti 1999; Silverstone 1983). The progression in either disease may be attributed to a change in the environmental equilibrium that favours disease conditions. For example, gingivitis has been shown to be a risk factor in the clinical course of chronic periodontitis (Schatzle 2009); and it is important to treat gingivitis when inflammation is only in the gingival tissues and has not affected other parts of the periodontal system (Mariotti 1999). Early carious lesions can be arrested in the enamel and may or may not progress to the dentine depending on the dynamic equilibrium between demineralisation and remineralisation (Marinho 2002; Marinho 2002a; Marinho 2003).

Periodontal diseases and dental caries are found in high-, middle- and low-income countries. Although the incidence of periodontal disease and dental caries differs, based on regional, social and genetic factors, the prevention of these diseases has a significant healthcare and economic benefit, to both society as a whole and individual patients. The regular and effective removal of dental plaque is important in the prevention of these common oral diseases. In conjunction with professional plaque removal services, for example by a dental hygienist, self administered daily mechanical disruption and removal of dental plaque is considered important for oral health maintenance (Needleman 2005; Rosing 2006; Zaborskis 2010). Besides toothbrushing, which is the most common method for removing dental plaque (Addy 1986; Mak 2011; Richardson 1977), different interdental aids to plaque removal, for example, dental floss, interdental brushes and other interdental cleaning aids, are widely available and are recommended to be used in addition to toothbrushing (Bosma 2011; Särner 2010). Whilst floss can be used in all interdental spaces, the interdental brush and other interdental cleaning aids require sufficient interdental space to be used by patients. The choice of interdental cleaning aid will depend on the size of the space and the ability of the patient to use it.

Description of the condition

Periodontal diseases

Periodontal diseases are multifactorial oral health conditions (Llorente 2006; Timmerman 2006), consisting of a diverse family of pathological conditions affecting the periodontium (a collective term that comprises gingival tissue, periodontal ligament, cementum and alveolar bone), that commonly affect the population (Adult Dental Health Survey 2009; Eke 2012). Periodontal diseases include two main conditions: gingivitis and periodontitis. Gingivitis is defined as the presence of gingival inflammation without loss of connective tissue attachment and appears as red, puffy, shiny gums that bleed easily (Mariotti 1999). Periodontitis is defined as inflammation and destruction of the supportive tissues of teeth and is, by its behaviour, characterised as aggressive or chronic (Armitage 1999). Susceptibility to periodontal disease is variable and depends upon the interaction of various risk factors, for example genetic makeup, smoking, stress, immunocompromising diseases, immunosuppressive drugs, and certain systemic diseases, for example diabetes (Van Dyke 2005). Socioeconomic factors, for instance educational and income levels, have been found to be strongly associated with the prevalence and severity of periodontal diseases (Borrell 2012).

The prevalence of periodontitis is difficult to establish across studies because of non-standardised criteria, different study population characteristics, different clinical measurements, and the use of partial versus full mouth examinations (Cobb 2009; Savage 2009). Of particular concern are the differing definitions and clinical measurements being used (Cobb 2009; Savage 2009). Recent national studies have assessed oral cleanliness, periodontal disease and oral hygiene behaviour. In the UK only 17% of adults had healthy gums; 66% had visible plaque; and of those with plaque, 65% had bleeding gums compared with 33% with no plaque (Adult Dental Health Survey 2009). Whilst more severe forms of periodontal disease, with alveolar bone loss, are much less common, gingivitis is prevalent at all ages and is the most common form of periodontal disease (Mariotti 1999). Some form of periodontitis affects the majority of the population (Adult Dental Health Survey 2009; Eke 2012). Periodontitis can influence quality of life through psychosocial impacts as a result of negative effects on comfort, function, appearance and socialisation (Durham 2013; Needleman 2004). It can also lead to tooth loss (Broadbent 2011), which negatively impacts on both aesthetics and function. Since periodontal diseases are inflammatory, bacterially mediated diseases that trigger the host's immune system, it is postulated that the individual's oral health status may influence their systemic health. Studies have shown some possible associations between periodontal diseases and coronary heart disease (Machuca 2012), hyperlipidaemia (Fentoğlu 2012), preterm births (Huck 2011), and lack of glycaemic control in people with diabetes mellitus (Columbo 2012; Simpson 2010).

Dental plaque is the primary aetiological factor in the development of periodontal diseases and dental caries (Dalwai 2006; Kuramitsu 2007; Marsh 2006; Periasamy 2009; Selwitz 2007). Dental plaque is a highly organised and specialised biofilm comprising of an intercellular matrix consisting of various micro-organisms and their by-products. The bacteria found within dental plaque mutually support each other, using chemical messengers, in a complex and highly evolved community, that protects them from an individual's immune system and chemical agents such as antimicrobial mouth rinses. Bacteria in biofilm are 1000 to 1500 times more resistant to antibiotics than in their free-floating state, reducing the effectiveness of chemical agents as a solo treatment option. Therefore disruption of the oral biofilm via mechanical methods remains one of the best treatment options (Chandki 2011). Calcified plaque (calculus) is not involved in the pathogenesis of periodontal disease but it provides an ideal surface to collect further dental plaque and acts as a 'retention web' for bacteria, protecting

plaque from appropriate preventive and therapeutic periodontal measures (Ismail 1994; Lindhe 2003).

Dental caries

Dental caries is a multifactorial, bacteriologically mediated, chronic disease (Addy 1986; Richardson 1977; Rickard 2004). According to the World Oral Health Report 2003 (Petersen 2003), dental caries affects 60% to 90% of school children and the vast majority of adults, making it one of the most common diseases in the world population (WHO 1990). Although the prevalence and severity of dental caries in most industrialised countries has substantially decreased in the past two decades (Marthaler 1996), this preventable disease continues to be a common public health problem for other parts of the world (Burt 1998).

Deep pits and fissures, as well as interdental spaces, represent areas of increased risk for the collection and accumulation of dental plaque and are therefore regarded as susceptible tooth surfaces for the occurrence of carious lesions. The presence and growth of dental plaque is further encouraged by compromised host response factors, for example reduced salivary flow (hyposalivation) (Murray 1989). Fermentation of sugars by cariogenic bacteria within the plaque results in localised demineralisation of the tooth surface, which may ultimately result in cavity formation (Marsh 2006; Selwitz 2007).

Patients with carious teeth may experience pain and discomfort (Milsom 2002; Shepherd 1999); and, if left untreated, may lose their teeth. In the United Kingdom, tooth decay accounts for almost half of all dental extractions performed (NHS 1999).

Prevention of dental caries and periodontal disease is generally regarded as a priority for oral healthcare professionals because it is more cost-effective than treating it (Brown 2002; Burt 1998). Effective plaque control by toothbrushing is a key self care strategy for oral health (Addy 1986; Richardson 1977). Patients routinely use toothbrushes to remove supragingival dental plaque, but toothbrushes are unable to penetrate the interdental area where periodontal disease first develops and is prevalent (Asadoorian 2006; Berchier 2008; Berglund 1990; Casey 1988). Interdental plaque is more prevalent (Lindhe 2003), forms more readily (Igarashi 1989) and is more acidogenic than plaque on other tooth surfaces in the mouth. Therefore interdental cleaning is often recommended as an adjunctive self care therapy, particularly when caries risk is increased (Sarner 2010; Wright 1977).

Description of the intervention

Dental floss

The concept of interdental cleaning with a filamentous material was first introduced by Levi Spear Parmly, as a measure for preventing dental disease together with a dentifrice and toothbrush (Parmly 1819). Unwaxed silk floss was first produced in 1882, by Codman & Shurtleff, but it was Johnson & Johnson who made silk floss widely available from 1887, as a by-product of sterile silk leftover from the manufacture of sterile sutures (Johnson).

Certain organisations, for example the American Dental Association, recommend that children's teeth are flossed as soon as they have two teeth that touch. However, studies that measure compliance show that few children have their teeth flossed or use floss: a study in West Virginia found that only 21% of children had their teeth flossed (Wiener 2009). When measures are taken to increase compliance, for example using behavioural change techniques, then the proportion of adolescent flossing increases (Gholami 2015).

Since dental floss is able to remove some interproximal plaque (Asadoorian 2006; Waerhaug 1981), it is thought that frequent regular dental flossing will reduce the risk of periodontal disease and interproximal caries (Hujoel 2006). Daily dental flossing in combination with toothbrushing for the prevention of periodontal disease and caries is frequently recommended (Bagramian 2009; Brothwell 1998). However, patient compliance with daily dental flossing is low (Schuz 2009). Patients attribute their lack of dental flossing compliance to lack of motivation and difficulties using floss (Asadoorian 2006). A study of a cohort of young people at ages 15, 18 and 26 found that at age 26, only 51% of both females and males believed that using dental floss was important, with females rating flossing more important than males (Broadbent 2006).

Interdental brushes

Interdental brushes are small cylindrical or cone-shaped bristles on a thin wire that may be inserted between the teeth. They have soft nylon filaments aligned at right angles to a central stiffened rod, often twisted stainless steel wire, very similar to a bottle brush. Interdental brushes used for cleaning around implants have coated wire to avoid scratching the implants or causing galvanic shock. They are available in a range of different widths to match the interdental space and their shape can be conical or cylindrical. Most are round in section, although interdental brushes with a more triangular cross-section can also be found in the market. Originally, interdental brushes were recommended by dental professionals to patients with large embrasure spaces between the teeth (Slot 2008; Waerhaug 1976), caused by the loss of interdental papilla mainly due to periodontal destruction. Patients who had interdental papillae that filled the embrasure space were usually recommended to use dental floss as an interdental cleansing tool. However, with the greater range of interdental brush sizes and cross-sectional diameters now available, they are considered a potentially suitable alternative to dental floss for patients who have interdental papillae that fill the interdental space (Imai 2011). Daily dental flossing adherence is low among patients because it requires a certain degree of dexterity and motivation (Asadoorian 2006), whereas interdental brushes have been shown as being easier to use and are therefore preferred by patients (Christou 1998; Imai 2010). Furthermore, when compared to dental floss, they are thought to be more effective in plaque removal because the bristles fill the embrasure and are able to deplaque the invaginated areas on the tooth and root surfaces (Bergenholtz 1984; Christou 1998; Imai 2011; Jackson 2006; Kiger 1991; Waerhaug 1976). However, there

are conflicting study results regarding the efficacy of interdental brushes in the reduction of clinical parameters of gingival inflammation (Jackson 2006; Noorlin 2007); and whether they are only suitable for patients with moderate to severe attachment loss and open embrasures, or whether they are a suitable aid for healthy patients to prevent gingivitis who have sufficient interdental space to accommodate them (Gjermo 1970; Imai 2011).

Tooth cleaning sticks

Sticks and twigs, composed of bone, ivory, metal, plastic, quills, wood and other substances, have been used for cleaning tooth surfaces and interdentally since prehistoric times (Christen 2003). The continuing use of hard materials for cleaning interdentally has been questioned (Mandel 1990); however, they continue to be used in different parts of the world. The meswak (or miswak) is one of the most widely used tooth cleaning sticks (Saha 2012), however it is important to differentiate its use between cleaning tooth surfaces and interdentally (Furuta 2011). Toothpicks continue to be used, particularly in the United States and Scandinavia, predominantly in older age groups (Sarner 2010), whereas dental floss and interdental brushes are more likely to be used by younger people. Toothpicks are commonly used in East Asia such as in China, Korea and Japan, though the main purpose is to remove food debris in the interdental areas. Interdental rubber tip stimulators, usually consisting of a carrying handle and disposable rubber tip stimulator, are readily available and are designed to stimulate gingival blood flow and remove interdental plaque.

Oral irrigators

Oral irrigation with water under pressure has been available for just over fifty years (Lyle 2012), and the benefits are described as the removal of biofilm from tooth surfaces and bacteria from periodontal pockets. Oral irrigators were first designed to be used supragingivally, using water pressure to displace and remove plaque, relying on pressure to irrigate subgingival regions (Goyal 2012). Since then, various tips have been designed that may be used subgingivally and several manufacturers provide products to do this.

How the intervention might work

Periodontal diseases

Gingival diseases are classified as one of the periodontal diseases (Armitage 1999), and are categorised as either dental plaque-induced diseases or non-plaque-induced gingival lesions. Gingival inflammation, gingivitis, induced by dental plaque is an inflammatory response of the gingival tissues caused by bacteria in dental plaque (Page 1986), and characterised by swelling, redness and bleeding on probing. If dental plaque is left in place for more than two weeks, then gingivitis will occur (Loe 1965). The severity of gingivitis can be modified by factors other than plaque (Trombelli 2013).

Periodontal diseases are complex interactions of bacteria and the immune system (Sanz 2011); and dental plaque is the primary aetiological factor (Marsh 2006). Dental plaque may be either supra-gingival or sub-gingival and the plaque biofilm comprises different bacterial colonies at the supra-gingival or sub-gingival levels.

Removal of dental plaque by mechanical interdental cleaning will remove the primary aetiological factor for gingivitis and periodontal disease.

Dental caries

Dental plaque contains many bacterial species which are acidogenic. In 1890, Miller published 'The microorganisms of the human mouth' which postulated that oral bacteria found in plaque were acidogenic, but as no specific bacteria were implicated it became known as the "non-specific plaque hypothesis" (Ring 2002). Later, Loesche 1976 postulated a "specific plaque theory", implicating *Streptococcus mutans* and *Lactobacillus acidophilus* as the primary bacteria involved in caries generation. Since then, the importance of the plaque biofilm has been recognised and an "ecological plaque hypothesis" proposed (Marsh 1994).

Acidogenic plaque bacteria utilise dietary sugars to demineralise dental tissues, which may progress into carious tooth lesions. The most susceptible regions of teeth to caries are the occlusal and interdental surfaces (Demirci 2010). Removal of dental plaque by mechanical interdental cleaning should reduce the frequency and degree of demineralisation interproximally and lead to decreased caries incidence.

Why it is important to do this review

Mechanical interdental cleaning, using either dental floss, interdental brushes or tooth cleaning sticks are widely recommended and advertised for interdental cleaning. It is unclear whether there is a benefit in mechanical interdental cleaning as an adjunct to toothbrushing and if a particular type of interdental cleaning is superior to others. Also, it is unknown what the benefits may be for children and adolescents.

A systematic review and meta-analysis, combining the results of randomised controlled trials, will provide health care commissioners, practitioners and consumers with evidence about the effectiveness of mechanical interdental cleaning on oral health.

This review, which includes the previous reviews on flossing (0245) and interdental brushing (0257), was considered to be a clinically important topic to maintain on *The Cochrane Library* when the prioritisation exercise was undertaken by the Cochrane Oral Health Group.

OBJECTIVES

To evaluate the effectiveness of mechanical interdental cleaning (flossing, interdental brushing, tooth cleaning sticks and stimulators, oral irrigators), in addition to toothbrushing, compared with toothbrushing alone, for the prevention and control of:

1. periodontal diseases (gingivitis and periodontitis)

2. dental caries

3. dental plaque

This also includes assessing the safety of mechanical interdental cleaning procedures, in terms of harms and adverse effects, balancing important benefits against important harms.

A secondary objective will compare the different mechanical cleaning procedures with each other.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (including split-mouth design and cross-over trials) and cluster-randomised trials. Data from both periods of a cross-over trial will be included only if there is a washout period of at least two weeks before the cross-over. Studies will be included regardless of their publication status and language.

Types of participants

The review will include studies of dentate participants regardless of age, race, gender, socioeconomic status, geographical location, background exposure to fluoride, initial dental health status, setting or time of the intervention. Studies will be excluded if the majority of participants have any orthodontic appliances. Likewise, studies will be excluded if participants were selected on the basis of special (general or oral) health conditions (for example, severely immunocompromised patients), or if the majority of participants had severe periodontal disease.

Types of interventions

We will include all trials that compare a combination of toothbrushing and any interdental mechanical dental cleaning procedure, with toothbrushing alone, or with another mechanical dental cleaning procedure. Interventions may be self performed, supervised or unsupervised.

We will exclude studies where any of the intervention or control groups receive any additional active agent(s) (i.e. caries preventive agents) as part of the study (e.g. chlorhexidine mouthwash, additional fluoride-based procedures, oral hygiene procedures, xylitol chewing gum) in addition to interdental cleaning procedures or toothbrushing. However, we will include studies using floss impregnated with active agents such as chlorhexidine or fluoride. We will include studies that include participants receiving additional measures as part of their routine oral care, such as oral hygiene advice, supervised brushing, fissure sealants, etc.

The minimum duration of the intervention is set at 4 weeks for periodontal diseases and 24 weeks for dental caries.

Types of outcome measures

Primary outcomes

We considered the following outcomes to be most relevant and important to clinicians and patients.

- Gingivitis - assessed by gingival indices (both inflammatory and bleeding);
- Periodontitis - assessed by clinical attachment loss and pocket probing depth;
- Interproximal caries - assessed by (a) progression of caries into enamel or dentine, (b) change in decayed, missing and filled tooth surfaces (D(M)FS) index, (c) radiographic evidence. Studies had to contain explicit criteria for diagnosing dental caries. As caries increment could be reported differently in different trials, we used a set of a priori rules to choose the primary outcome data for analysis from each study (Marinho 2003);
- Plaque - assessed by plaque scores or indices.

Secondary outcomes

- Harms and adverse effects;
- Halitosis;
- Patient satisfaction;
- Cost of intervention.

Search methods for identification of studies

For the identification of studies included or considered for this review, we will develop detailed search strategies for each database searched. These will be based on the search strategy developed for MEDLINE (OVID) but revised appropriately for each database. The search strategy will use a combination of controlled vocabulary and free text terms and will be linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials (RCTs) in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011) (Higgins 2011). Details of the proposed MEDLINE search are provided in Appendix 1. The searches of EMBASE and CINAHL will be linked to the Cochrane Oral Health Group filters for identifying RCTs.

Electronic searches

We will search the following databases:

- The Cochrane Oral Health Group Trials Register (to date);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, current issue);
- MEDLINE via OVID (1946 to date) (see Appendix 1);
- EMBASE via OVID (1980 to date);
- CINAHL via EBSCO (1937 to date);
- Web of Science Conference Proceedings (1990 to date).

No restrictions will be placed on language or date of publication in the searches of the electronic databases.

Searching other resources

We will search the following databases for ongoing trials:

- US National Institutes of Health Trials Register (http://clinicaltrials.gov) (to date);
- The WHO Clinical Trials Registry Platform (http://apps.who.int/trialsearch/default.aspx) (to date).

Only handsearching done as part of the Cochrane Worldwide Handsearching Programme and uploaded to CENTRAL will be included.

Data collection and analysis

Selection of studies

Two review authors independently will carry out the selection of studies and make decisions about eligibility; one of them a methodologist and the other a topic area specialist. If the relevance of a study report is unclear, we will review the full text and resolve all disagreements by discussion with other authors.

Data extraction and management

At least two review authors will independently extract data; at least one of them a methodologist and one a topic area specialist. We will compare the extracted data and identify disagreements, which we will then resolve by consensus. The review authors will not be blinded to the authors, interventions or results obtained in the included studies.

We will extract and enter the following data into the customised collection form:

(1) Study characteristics: study design, including details of how the study differs from standard parallel-group design (e.g. split-mouth or cross-over); date and duration of study; setting of the study.

(2) Participants:

- number enrolled, randomised and recruited (by study group);
- inclusion and exclusion criteria;
- demographic characteristics of participants: age, gender, country of origin, ethnicity, gender, socioeconomic status, comorbidity, caries and periodontal disease risk status. We will record demographic characteristics for the study as a whole and for each intervention group, if available.

(3) Intervention: we will collect the following details of the intervention and control groups:

- type of interdental cleaning procedure, including type of toothbrush (powered or manual) and type of toothpaste (with or without fluoride);
- frequency of interdental cleaning procedure, duration of the intervention period and;
- were the participants trained/instructed how to brush interdentally, floss or toothbrush, or a combination of all three; and by whom?;
- length of follow-up, loss to follow-up;
- assessment of adherence;
- level of fluoride in the water supply.

(4) Outcomes:

- detailed description of the outcomes of interest (both beneficial and adverse), including the definition and timing of measurement;
- methods of assessment.

Furthermore, we will list other outcomes reported in the included studies; however the results will only be extracted for the prespecified outcomes of interest.

We will also extract data on funding sources if reported.

We have already designed a data extraction form for a similar review (Sambunjak 2011).

Assessment of risk of bias in included studies

We will carry out the assessment of risk of bias by using Cochrane's 'Risk of bias' tool as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The tool addresses the six following domains: sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting, and other issues. Since blinding of the study participants for the interventions of interest is not usually possible, the primary consideration will be given to the blinding of the outcome assessors. For split-mouth and cross-over designs, assessment of risk of bias will include additional considerations such as suitability of the design, and risk of carry-over or spill-over effects. We will record each piece of information extracted for the 'Risk of bias' tool together with the precise source of this information and use this to assign a judgement of low, high or unclear risk of bias for each domain within each included study. We will test the data collection forms and assessments of the risk of bias on a pilot sample of articles. The assessors will not be blinded to the names of the authors, institutions, journal or

results of a study. At least two review authors independently, and in duplicate, will carry out the assessment of risk of bias; one of them a methodologist and the other a topic area specialist. If any piece of information important for the assessment of risk of bias is missing in the included reports, we will attempt to contact the study investigators and obtain the required information by use of open-ended questions.

Summarising risk of bias for a study

After taking into account the additional information provided by the authors of the trials, we will group the studies into the following categories. We will assume that the risk of bias was the same for all outcomes and will assess each study as follows:

Risk of bias	Interpretation	Within a study	Across studies
Low risk of bias	Plausible bias unlikely to alter the results seriously	Low risk of bias for all key domains	Most information is from studies at low risk of bias
Unclear risk of bias	Plausible bias that raises some doubt about the results	Unclear risk of bias for one or more key domains	Most information is from studies at low or unclear risk of bias
High risk of bias	Plausible bias that seriously weakens confidence in the results	High risk of bias for one or more key domains	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of results

Measures of treatment effect

For gingivitis and plaque outcomes, we expect the measures of treatment effect to mostly be continuous. In such cases, the mean difference (or difference in means) and standardised mean difference, when combining different clinical indices, will be the effect measures used. We will calculate the corresponding 95% confidence intervals (CI) for each study.

Clinical attachment loss can be a continuous measure, but the incidence is often so low that it can be dichotomised on a patient basis and considered a binary measure. If the binary data is provided we plan to use risk ratios together with 95% CI to combine dichotomous data.

For caries outcomes, we will calculate the prevented fraction (PF) where appropriate. The PF is expressed as the mean increment in the control group minus the mean increment in the intervention group divided by the mean increment in the control group, i.e. the caries increment in the treatment group expressed as a percentage of the control group.

We will enter data from cross-over, split-mouth studies, and for the prevented fraction, into RevMan (Review Manager (RevMan)) using the generic inverse variance outcome type.

When full-mouth and interdental indices are presented, we will use the interdental indices for the analyses.

For the studies that use both gingival and bleeding indices, we will use gingivitis scores in the meta-analyses because gingivitis indices assess clinical signs of inflammation in the gingivae and are based on visual (non-invasive) and bleeding (invasive) components (Armitage 1996).

As for the bleeding indices, for studies in which both bleeding on probing (BOP) and Eastman Interdental Bleeding Index (EIBI) are used, we will include EIBI in the meta-analyses. The suitability of the EIBI is justified by its reproducibility and high inter-examiner and intra-examiner reliability (Blieden 1992).

We will only use data with at least six months' follow-up for change in clinical attachment loss, and at least six months' follow-up for the assessment of interproximal caries.

Unit of analysis issues

The unit of analysis will be individual patients or groups of measuring sites within individual patients (e.g. interproximal sites: proportion of sites that have bleeding averaged over the number of patients). Contact with study authors may be necessary to obtain data in the right form. We will analyse split-mouth, cross-over and cluster trials taking the clustering into account as described in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Dealing with missing data

As described in Table 16.1.a in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), there are several types of missing data in a systematic review or meta-analysis. The problems of missing studies and outcomes will be addressed in the Assessment of reporting biases part of this review. A common problem is missing summary data, such as the standard deviations for continuous outcomes, or separate sample sizes for each intervention group. Missing summary data will not be a reason to exclude a study from the review and we will use the methods outlined in section 16.1.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* for imputing missing standard deviations (Higgins 2011).

For the data judged to be 'missing at random', i.e. their being missing is unrelated to their actual values, analyses including only the available data will be conducted. If data are judged to be 'not missing at random', we will perform a sensitivity analysis to assess how the changes in assumptions might have affected the results. The potential impact of missing data on the findings of the review will be addressed in the 'Discussion' section of the review.

Assessment of heterogeneity

Prior to meta-analysis, we will first assess studies for clinical homogeneity with respect to type of therapy, control group and the outcomes. Clinically heterogeneous studies will not be combined in the analysis. For studies judged as clinically homogeneous, we will test statistical heterogeneity using the Chi^2 test and I^2 statistic. We will interpret a Chi^2 test resulting in a P value less than 0.10 as indicating significant statistical heterogeneity. In order to assess and quantify the possible magnitude of inconsistency (i.e. heterogeneity) across studies, we will use the I^2 statistic with a rough guide for interpretation as follows: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; 75% to 100% may represent considerable heterogeneity.

Assessment of reporting biases

We will assess possible reporting biases on two levels: within-study and between-study. Within-study selective outcome reporting will be examined as a part of the overall 'Risk of bias' assessment (*see* Assessment of risk of bias in included studies). We will attempt to find protocols of included studies and compare the outcomes stated in the protocols with those reported in the publications. If protocols are not found, we will compare the outcomes listed in the methods sections in a publication against those whose results are reported. In case some indications of reporting bias are found, we will contact the study authors for clarification. If there are at least 10 studies included in a meta-analysis, we will create a funnel plot of effect estimates against their standard errors to assess a possible between-study reporting bias. If an asymmetry of the funnel plot is found either by inspection or statistical tests, we will consider possible explanations and take this into account in the interpretation of the overall estimate of treatment effects.

Data synthesis

Meta-analysis will be undertaken including only the studies reporting the same outcomes. Since there will be a number of different indices measuring what we consider the same basic concept (plaque or gingivitis), we will use the standardised mean difference (SMD), along with the appropriate 95% CI, to combine the results of different indices in meta-analysis. Some studies measure plaque and gingivitis on selected sites and we will use indices based on these data if the interproximal site data is not available. Risk ratios will be combined for binary data. As considerable heterogeneity is expected in the included studies, we will undertake a random-effects model to be used as a primary method of meta-analysis.

Subgroup analysis and investigation of heterogeneity

We planned the following subgroup analyses.

- Age and dentition (primary dentition versus permanent dentition;
- Periodontal status;
- Trained (instructed) versus untrained (uninstructed) interdental cleaning;
- Funded and unfunded studies.

Sensitivity analysis

The primary meta-analysis will include all eligible studies irrespective of their risk of bias. Sensitivity analyses will be conducted:

- excluding studies at high risk of bias (excluding the patient blinding from this overall study level assessment of risk of bias);
- excluding studies with estimated standard deviations;
- excluding studies with split-mouth and cross-over designs.

Summarising findings and assessing the quality of the evidence

We will adopt the GRADE system for evaluating the quality of the evidence of systematic reviews (Guyatt 2008; Guyatt 2008a; Higgins 2011), and use it to construct 'Summary of findings' tables. We will assess the quality of the body of evidence with reference to the overall risk of bias of the included studies, the directness of the evidence, the inconsistency of the results, the precision of the estimates and the risk of publication bias. We will classify the quality of the body of evidence into four categories: high, moderate, low and very low.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE (OVID) search strategy

1. exp TOOTH DEMINERALIZATION/
2. (caries or carious).mp.
3. (teeth adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
4. (tooth adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
5. (dental adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
6. (enamel adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
7. (dentin$ adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
8. (root$ adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
9. Dental plaque/
10. Dental deposits/
11. ((teeth or tooth or dental or enamel or dentin) and plaque).mp.
12. ((tooth or teeth or dental) adj5 (stain$ or discolor$ or discolour$ or calculus or tartar)).mp.

13. exp DENTAL HEALTH SURVEYS/
14. ("DMF Index" or "Dental Plaque Index" or "Periodontal Index" or "Papillary Bleeding Index").mp.
15. (dental adj2 deposit$).mp.
16. exp Periodontal Diseases/
17. periodont$.mp.
18. gingivit$.mp.
19. (gingiva$ adj3 pocket$).mp.
20. ((blood or bleed$) adj4 prob$).mp.
21. (gingival$ adj5 (disease$ or blood$ or bleed$ or inflamm$ or index or hemorrhag$ or haemorrhag$)).mp.
22. (papilla$ adj3 (bleed$ or index$)).mp.
23. "bleeding index".mp.
24. ((pocket$ or probe or probing) adj2 depth).mp.
25. "attachment loss".mp.
26. or/1-25
27. exp Dental Devices, Home Care/
28. Toothbrushing/
29. ((interdental adj3 brush$) or (inter-dental adj3 brush$) or (interspace adj3 brush$) or (inter-space adj3 brush$) or (interproximal adj3 brush$) or (inter-proximal adj3 brush$)).mp.
30. ((interdental adj3 clean$) or (inter-dental adj3 clean$) or (interspace adj3 clean$) or (inter-space adj3 clean)).mp.
31. ((interproximal adj3 clean$) or (inter-proximal adj3 clean$)).mp.
32. ((interdental adj3 aid$) or (inter-dental adj3 aid$)).mp.
33. (toothbrush$ or tooth-brush$ or "tooth brush$").mp.
34. Proxabrush.mp.
35. (floss$ or Superfloss or Ultrafloss or Airfloss).mp
36. (dental adj5 tape$).mp.
37. (miswak$ or meswak$ or woodstick$ or toothpick$ or "wood stick$" or "tooth pick$" or woodpoint$ or "wood point$").mp.
38. ("gingival stimulator$" or "rubber tip stimulator$" or "gum stimulator$" or "Butler GUM" or Stimu-gum or "interproximal stimulator$" or "wedge stimulator$" or "wooden stimulator$" or "interdental stimulator" or "subgingival tip$").mp.
39. ((oral or water or subgingival or dental) adj2 irrigat$).mp.
40. ("water pick$" or waterpick$).mp.
41. (Oxyjet or Waterpik or "Water Pik" or "Oral Breeze" or PowerFloss or "Hydro Floss" or "Water Jet" or Aquajet or Interplak or h2ofloss or "Perio Pik" or "Pik Pocket" or Pickpocket$ or Softpick or Softpik).mp.
42. or/27-41
43. 26 and 42

The above subject search will be linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomized trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of *The Cochrane Handbook for Systematic Reviews of Interventions,* Version 5.1.0 [updated March 2011] (Higgins 2011).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

CONTRIBUTIONS OF AUTHORS

Trevor Johnson: writing protocol, screening search results, undertaking data extraction, risk of bias assessment, writing review

Helen Worthington: writing protocol, undertaking data analysis, writing review

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Dario Sambunjak: writing protocol, undertaking data extraction, 'Risk of bias' assessment, writing review

Pauline Imai: writing protocol, screening search results, undertaking data extraction, 'Risk of bias' assessment, writing review

DECLARATIONS OF INTEREST

Trevor Johnson: no interests to declare

Helen Worthington: possible author on some included studies (these are to be assessed by other authors)

Jan Clarkson: no interests to declare

Tina Poklepovic Pericic: no interests to declare

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